



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,935	01/30/2001	Gerardo R. Vasta	4115-137 CIP	9125

23448 7590 05/30/2003

INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/771,935	VASTA ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1634

1. The first line of the specification should be amended to delete the statement that application 08/900,117 is a continuation-in-part of provisional application 60/023,345. The first line of the specification should be amended to indicate that this application claims the benefit of U.S.

Provisional Application No. 60/023,345. See MPEP 201.11.

2. The disclosure is objected to because of the following informalities:

In claim 2, “synthesizing **and** oligonucleotide” should read “synthesizing **an** oligonucleotide”.

In claims 4, 6 and 12, a "." should be inserted following "region". See MPEP 608.01(m).

In claim 12, “and” should be inserted prior to the last sequence so that the claim recites a proper Markush group. See MPEP 2173.05(h).

3. Claims 2, 3, 5, 12, and 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 16-18 are indefinite and vague because the claims do not clarify the relationship between the steps of sequencing the NTS sequence and synthesizing an oligonucleotide.

Claims 2 and 16-18 are further indefinite over the recitation of “a nucleic acid sequence of SEQ ID NO: 18”. In view of the recitation of “a” and the limitation in claim 18 that the oligonucleotide is one of a pair of PCR primers, it is not clear as to whether this phrase refers to the full length sequence of SEQ ID NO: 18 or to fragments of any length of SEQ ID NO: 18.

Art Unit: 1634

Similarly, claims 3, 19 and 20, are indefinite over the recitation of “a nucleic acid sequence”. If Applicant intends to claim fragments of these sequences, then the claims should be amended to clarify this concept.

Claims 16 and 17 are indefinite and vague because it is not clear as to whether the claims are intended to include the steps of, e.g., amplifying a NTS sequence using primers or digesting DNA with a restriction enzyme or whether these recitations further characterize the isolated nucleic acids. In the former case, the claims should be amended to clarify, for example, “wherein the isolating step comprises...”

Claim 5 is indefinite over the recitation of “said nucleotide base” because this phrase lacks proper antecedent basis and it is unclear as to what is meant by a nucleotide base of an organism. While the claim does previously refer to a nucleotide base sequence it is unclear as to whether the “nucleotide base” is the same as or different from the “nucleotide base sequence.” This rejection may be overcome by amendment of the claim to refer to “said nucleotide base sequence.”

Claim 12 is indefinite and confusing because the sequence recited for SEQ ID NO: 6, 7, 11, 20, 21, 22 and 24 do not correspond to the sequences recited in the sequence listing. The SEQ ID Nos recited in the claims have been used examination herein. However, in response to this Office action, Applicant is required to amend the claims to recite the appropriate sequence next to each sequence identifier. It is also noted that the sequence listed for SEQ ID NO: 7 appears to be identical to the sequence listed for SEQ ID NO: 22.

Art Unit: 1634

Claim 14 is indefinite and unclear over the recitation that the nucleotide base sequence has type I and type II NTS sequences of SEQ ID NO: 24 and 25. Since SEQ ID NO: 24 and SEQ ID NO: 25 are 2 distinct sequences that located at the same position in the NTS, it is unclear as to what is meant by the organism having both of these sequences. For example, it is unclear as to whether the organism has 2 copies of the NTS, comprises either SEQ ID NO: 24 or SEQ ID NO: 25 or comprises some unspecified combination of SEQ ID NO: 24 and 25. Furthermore, the parenthesis should be removed from the claim because it is not clear as to whether the claim intends to refer to any NTS type I or type II sequence or to the specific NTS type I and II sequences of SEQ ID NO: 24 and 25.

Claim 15 is indefinite over the recitation of “said nucleic acid sequence” because this phrase lacks proper antecedent basis. While the claim previously refers to a “nucleotide base sequence”, the claim does not previously refer to a “nucleic acid sequence.”

Claim 19 is indefinite over the recitation of “wherein said microorganism is the genus *Perkinsus*.” While a microorganism may be a member of a genus, it is unclear as to what is intended to be meant by a microorganism that is a genus. This rejection may be overcome by amendment of the claim to recite, for example, “wherein said microorganism is from the genus *Perkinsus*.” Furthermore, it is unclear as to how claim 19 is intended to be further limiting from claim 3 since claim 3 previously recites “determining the identity of species of a microorganism of the genus *Perkinsus*.”

4.

PRIORITY

Art Unit: 1634

It is noted that the present application is entitled to only the present filing date for SEQ ID NO: 8, 9, 12-15, 18, 19, and 23-25. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). Accordingly, each of the pending claims are entitled only to the present filing date of January 30, 2001.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-12, and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Robledo (reference AX in the IDS of August 31, 2001).

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see Table 1). The reference also teaches nucleic acids comprising NTS type I and II sequences (see Figure 3). The nucleic acids of Robledo have the property of hybridizing to a NTS sequence

Art Unit: 1634

from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of SEQ ID NO: 1, 2, 3 and 18.

6. Claims 1, 4-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Marsh (reference AP in the IDS of August 31, 2001).

It is noted that the inventorship of the present application is distinct from the authorship of the Marsh et al reference.

Marsh teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Marsh comprises a sequence identical to present SEQ ID NO: 1 (see Figure 1). Marsh also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see page 577). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Marsh have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of SEQ ID NO: 1, 2, 3 and 18. Marsh also teaches the nucleic acids so that they may be used as probes (see page 578).

7. Claims 1, 2, and 4-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Robledo (October 2000/reference AY in the IDS of August 31, 2001).

It is noted that the inventorship of the present application is distinct from the authorship of the Robledo et al reference.

Art Unit: 1634

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of SEQ ID NO: 1, 2, 3 and 18. The reference also teaches methods of making an oligonucleotide comprising SEQ ID NO: 18 wherein said method comprises isolating DNA from a target organism, amplifying the nucleic acids of the NTS region of the target organism using primers, thereby synthesizing NTS nucleic acids comprising a sequence of SEQ ID NO: 18, sequencing said NTS nucleic acids and synthesizing PCR primers for amplifying *Perkinsus* sequences (see pages 973-974).

8. Claims 1 and 4-9, 14 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000).

It is noted that the inventorship of the present application is distinct from the authorship of the Robledo et al reference.

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). This sequence is considered to comprise NTS type I and II sequences. The

Art Unit: 1634

nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18 and comprise fragments of SEQ ID NO: 1, 2, 3 and 18.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (1999/references "AX") in view of Stokes (reference "BA").

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus marinus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides

Art Unit: 1634

(see Table 1). The reference also teaches nucleic acids comprising NTS type I and II sequences (see Figure 3). The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18.

Robledo teaches using the nucleic acid as a probe to detect *Perkinsus* sequences, but does not teach labeling the nucleic acid.

Stokes teaches labeling nucleic acid probes with digoxigenin to facilitate the detection of oyster pathogens (see, for example, page 351).

In view of the teachings of Stokes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to label the probes of Robledo with digoxigenin in order to have provided an effective means for facilitating the detection of *Perkinsus* nucleic acids.

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (2000/references "AY") in view of Stokes (reference "BA").

Robledo teaches isolated nucleic acids comprising the NTS region of *Perkinsus atlanticus*. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying *Perkinsus* NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18. The reference also teaches methods of making an oligonucleotide comprising SEQ ID NO: 18 wherein

Art Unit: 1634

said method comprises isolating DNA from a target organism, amplifying the nucleic acids of the NTS region of the target organism using primers, thereby synthesizing NTS nucleic acids comprising a sequence of SEQ ID NO: 18, sequencing said NTS nucleic acids and synthesizing PCR primers for amplifying Perkinsus sequences (see pages 973-974). Robledo does not teach labeling the nucleic acid.

Stokes teaches labeling nucleic acid probes with digoxigenin to facilitate the detection of oyster pathogens (see, for example, page 351).

In view of the teachings of Stokes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to label the probes of Robledo with digoxigenin in order to have provided an effective means for facilitating the detection of Perkinsus nucleic acids.

11. Claims 3, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (1999/references "AX") in view of the Stratagene Catalog (1988).

Robledo teaches isolated nucleic acids comprising the NTS region of Perkinsus marinus. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 1 (see Figure 2). Robledo also teaches primers for amplifying Perkinsus NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see Table 1). Robledo does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods

Art Unit: 1634

and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatability of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Robledo in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to amplify and detect Perkinsus nucleic acids.

12. Claims 3, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marsh in view of the Stratagene Catalog (1988).

Marsh teaches isolated nucleic acids comprising the NTS region of Perkinsus marinus. In particular, the nucleic acid of Marsh comprises a sequence identical to present SEQ ID NO: 1 (see Figure 1). Marsh also teaches primers for amplifying Perkinsus NTS sequences, including primers identical to present SEQ ID NO: 4 and 5 and of a length of 21 nucleotides (see page 577). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Marsh have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18. Marsh teaches using the nucleic acid as a probe to detect Perkinsus sequences, but does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to

Art Unit: 1634

perform an assay and ensure the quality and compatability of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Marsh in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to amplify and detect Perkinsus nucleic acids.

13. Claims 3, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robledo (2000/reference AY) in view of the Stratagene Catalog (1988).

Robledo teaches isolated nucleic acids comprising the NTS region of Perkinsus atlanticus. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18 (see Figure 2). Robledo also teaches primers for amplifying Perkinsus NTS sequences, including primers identical to present SEQ ID NO: 8 and 9 and of a length of 20 and 22 nucleotides, respectively (see page 974). This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18. Robledo does not teach packaging the primers in a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatability of the reagents to be used in the assay.

Art Unit: 1634

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers of Robledo in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to amplify and detect Perkinsus nucleic acids.

14. Claims 2, 9-11, 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) in view of Marsh.

Robledo teaches isolated nucleic acids comprising the NTS region of Perkinsus atlanticus. In particular, the nucleic acid of Robledo comprises a sequence identical to present SEQ ID NO: 18. This sequence is considered to comprise NTS type I and II sequences. The nucleic acids of Robledo have the property of hybridizing to a NTS sequence from an organism having a nucleotide sequence of any one of SEQ ID NO: 1, 2, 3, or 18. Robledo does not teach labeling the nucleic acids or generating primers from fragments of the nucleic acids.

However, Marsh also teaches isolated nucleic acids comprising the NTS region of Perkinsus marinus. Marsh teaches labeling the NTS sequences so that they may be used as probes. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have labeled the nucleic acids of Robledo in order to have allowed for the use of the nucleic acids as probes for detecting Perkinsus sequences. Furthermore, Marsh also teaches methods for synthesizing oligonucleotides comprising NTS sequences wherein the methods comprise isolating DNA from an organism, amplifying NTS sequences, determining the sequence of the amplified nucleic acids and preparing primers to the nucleic acids. Marsh (page

Art Unit: 1634

577) teaches preparing primers designed for the NTS region using the Whitehead PRIMER program and exemplifies 2 NTS primers of a length of 21 nucleotides. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to performed methods for synthesizing nucleic acids comprising a sequence of the NTS of Robledo and particularly to have synthesized NTS primers in order to have provided oligonucleotides and primers useful for amplifying and detecting Perkinsus sequences.

15. Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable Robledo (GenBank Accession No. AF140295/NCBI Database, April 17, 2000) in view of Marsh and further in view of the Stratagene Catalog.

The teachings of Robledo and Marsh are presented above. The combined references do not teach packing primers comprising sequences of GenBank Accession No. AF140295 into a kit.

However, reagent kits for performing DNA detection assays were conventional in the field of molecular biology at the time the invention was made. In particular, the Stratagene catalog discloses the general concept of kits for performing nucleic acid hybridization methods and discloses that kits provide the advantage of pre-assembling the specific reagents required to perform an assay and ensure the quality and compatability of the reagents to be used in the assay. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primers comprising sequences of GenBank

Art Unit: 1634

Accession No. AF140295 in a kit for the expected benefits of convenience and cost-effectiveness for practioners of the art wishing to amplify and detect Perkinsus nucleic acids.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,326,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of '485 are both inclusive of oligonucleotides comprising SEQ ID NO: 1-3 and fragments thereof. Furthermore, the present claims and the claims of '485 are

Art Unit: 1634

also inclusive of kits comprising the primers of SEQ ID NO: 4, 5, 10, 11, 20, 21 and 22 (referred to as SEQ ID NO: 4, 5, 8, 9, 10, 13 and 7 in '485, respectively). It is further noted that the oligonucleotides of SEQ ID NO: 1, 2 and 3 and the primers disclosed in '485 have the property of being capable of hybridizing to a NTS from a microorganism that comprises SEQ ID NO: 18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
May 27, 2003

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER